HL7 EHR Technical Committee

EHR Interoperability Project Team

17 September 2007

Gary L. Dickinson, Facilitator

EHR Interoperability Project Team

Areas of Focus

- "Coming to Terms" White Paper
  - Compilation and Analysis of Industry "Interoperability" Definitions
- EHR Interoperability Model (EHR/IM)
  - Characteristics of Interoperable EHR Records
  - Now: Draft Standard for Trial Use
- EHR Lifecycle Model (EHR/LM)
  - EHR Lifecycle Events
  - Now: Working Draft

EHR Interoperability Project Team

Areas of Focus, con't

- EHR/IM - CDAr2 Profile
- EHR/IM - Legal Profile
- ONC/AHIC/HITSP Use Case Alignment
  - EHRS/FM, PHRS/FM
  - EHR/IM, EHR/LM
- ISO 21089, "Trusted End-to-End Information Flows"
- Health Record Banking Alliance

Interoperability Definition

HL7

- "Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.
  - "'Functional' interoperability is the capability to reliably exchange information without error.
  - "'Semantic' interoperability is the ability to interpret, and, therefore, to make effective use of the information so exchanged."

Compilation and Analysis of Industry Interoperability Definitions

- Lead:
  - Pat Gibbons, Mayo Clinic
- Research/Reference/Foundation Project
- Compilation and Analysis
  - 100+ Definitions
  - Many sources, including HL7, ISO, IEEE, NAHIT, US Executive Order...
  - Approximately 50% - 50%
    - US and International

Compilation and Analysis

Key Aspects of Interoperability

- Technical Interoperability
  - Structure, syntax, reliable communication
- Semantic Interoperability
  - Full meaning preserved
- Process Interoperability
  - Integral to (healthcare delivery) process, work flow

Compilation and Analysis

Status

- "Coming to Terms" White Paper
  - Assessment and Findings
- Publication Package
  - White Paper & Slide Set Overview
  - Reference Spreadsheets
    - Source Summary and Acronyms
- Available on HL7 EHR TC Website
  - http://www.hl7.org/ehr

- To the question:
  "What is Interoperability?"
  - "Coming to Terms" White Paper

- To the point:
  "What is EHR Interoperability?"
  - HL7 EHR Interoperability Model - DSTU
  - HL7 EHR Lifecycle Model - Working Draft

EHR Interoperability Model

- Lead
  - Gary L. Dickinson
  - Consultant, representing CentriHealth
- DSTU Release 1
  - Passed Ballot, January 2007
  - Published, February 2007
- Available
  - http://www.hl7.org/ehr

EHR Interoperability Model

What is It?

- A consensus Draft Standard for Trial Use
- A common industry reference point
- A set of characteristics of (requirements for) interoperable EHRs, encompassing
  - WHAT (EHR Interoperability Characteristics) and
  - WHY (Rationale) but
  - NOT HOW (Architectures and Implementations)
- A concrete approach to EHR interoperability: technical, semantic and process

EHR Interoperability Model

What is It? con't

- A set of benchmarks to achieve persistent legal records
- A trust framework for key stakeholders
  - Patients/Consumers, Providers, Authors, Record Users...
- A structure to ensure record persistence and indelibility
  - End-to-end: point of record origination to each ultimate point of record access/use
  - Often traversing point-to-point record exchanges

EHR Interoperability Model

What is It? con't

- A context of the EHR as the immediate (concurrent) record of health(care)
  - Chronicle of health(care)
  - Documentation of health(care) Acts in Act Records
  - Creation of indelible Act Record entries in the persistent EHR

EHR Interoperability Model

What is It? con't

- An introduction of the Common EHR Unit of Record
  - An Act Record for each Act/Action
  - Sufficient to document all health(care) Acts
- A framework for Common Record Units (Act Records) to comprise the EHR

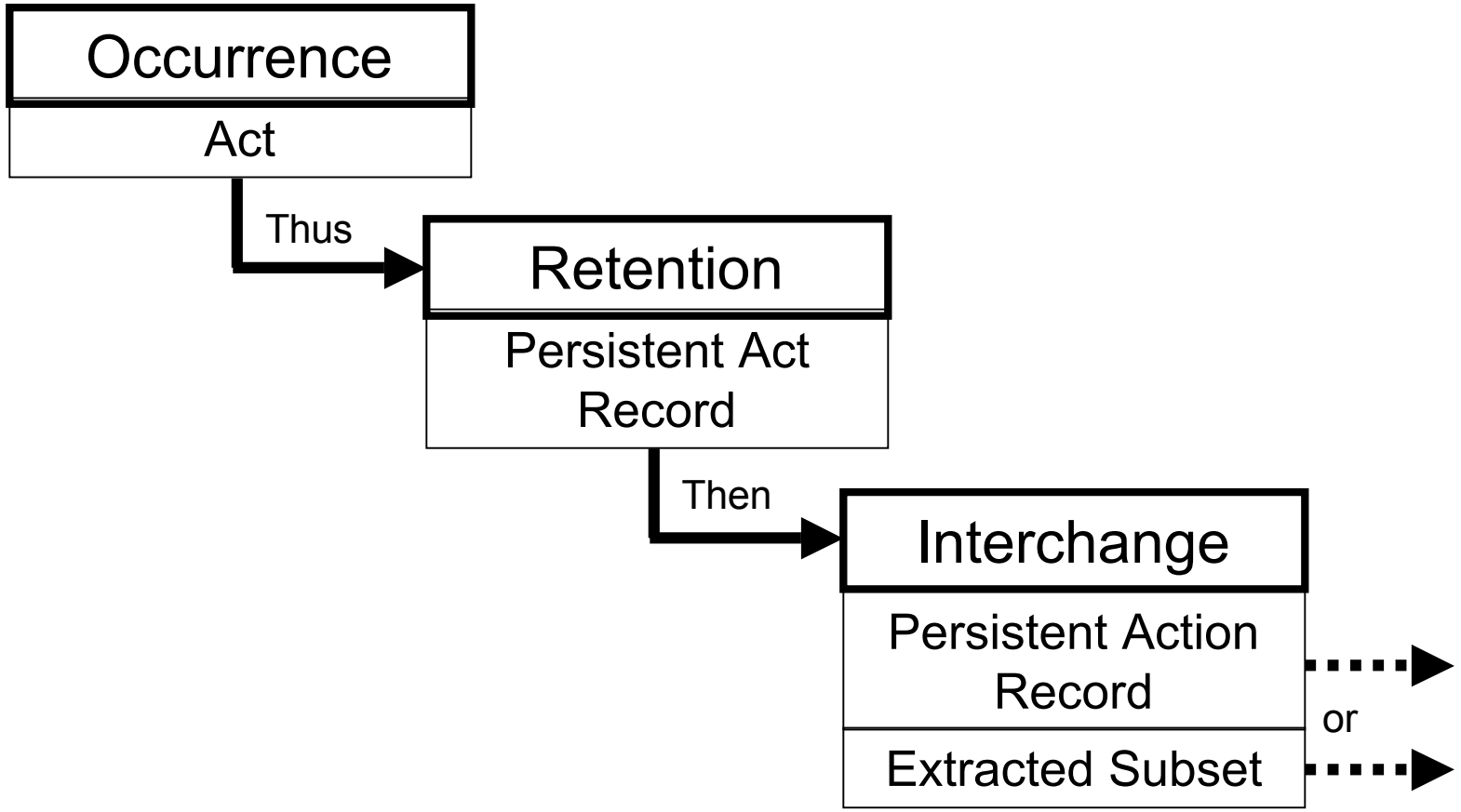
EHR Interoperability Model

What is It? con't

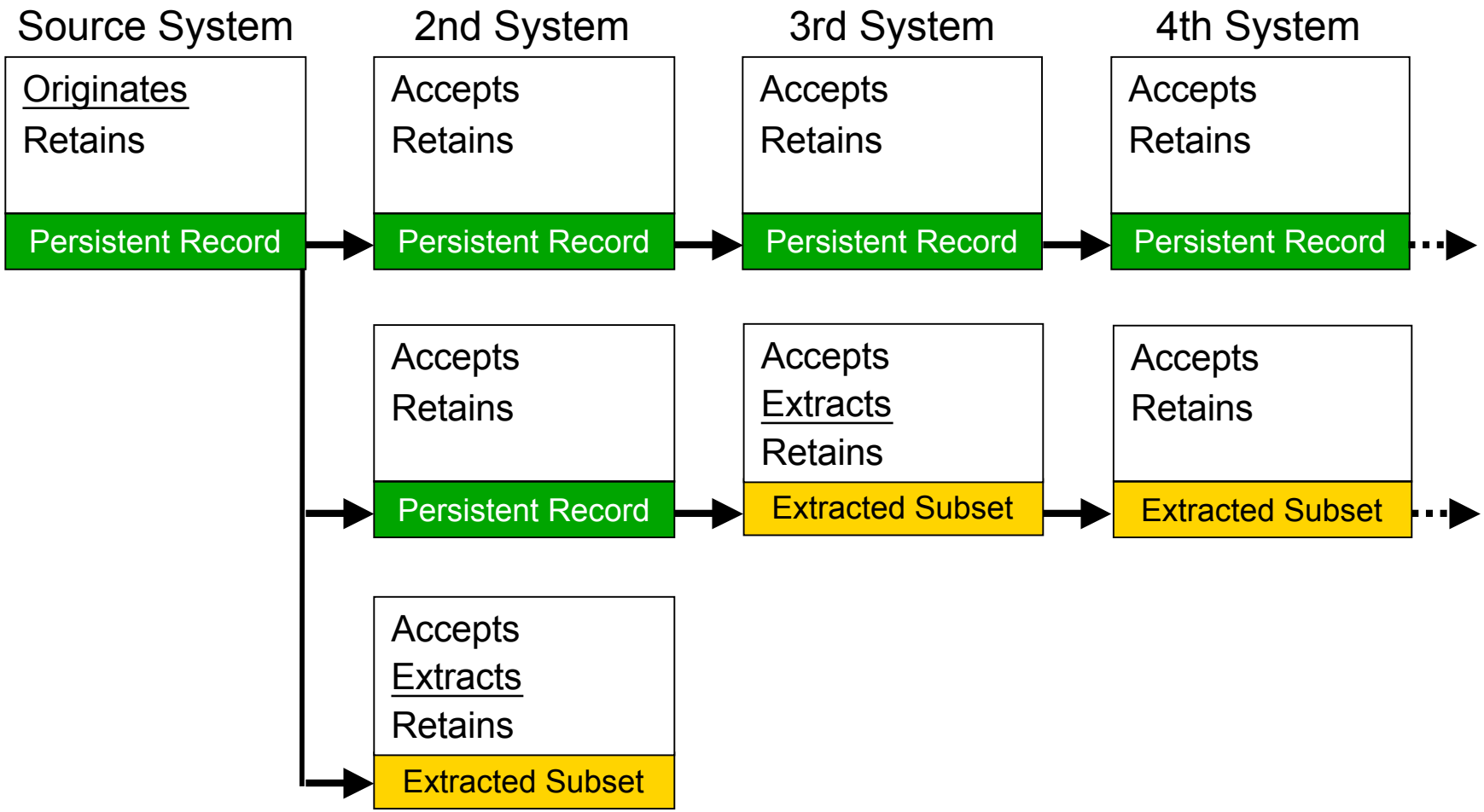
- A framework for conformance testing
  - Conformance criteria for record validation
  - Applicable to specific application roles
    - Record Source/Originator
    - Record Transmitter, Receiver
    - Interchange Mediator, Intermediary
- An approach which is technology and vendor neutral

EHR Interoperability Model

Act/Act Record/Interchange



Example Interchange Pattern
Persistent Records and Extracted Subsets



EHR Interoperability Model

Sections

1	Health(care) Delivery	
2	Health(care) Act	
3	Act Record	Common EHR Record Unit
4	Act Record Attributes	
5	Health Record	
6	Patient Encounter Record	
7	Patient Summary Record	
8	EHR Interoperability (Summary)	

EHR Interoperability Model

Section by Section

1 - Health(care) Delivery

- Healthcare delivery occurs as a process over time, it has a chronology
- Healthcare delivery is comprised of Actions occurring over time

2 - Health(care) Act

- An Act is a discrete instance of health(care delivery)
- An Act is performed or provided (i.e., service is rendered)
- An Act has Accountable Actor(s)
- An Act occurs at a date/time, it occurs at a location (e.g., at a specific point of service, point of care)

Health(care) Delivery	**Interoperable EHR**
Comprised of discrete Acts (Actions)	Comprised of persistent Act Records
Act Occurs →	Act is documented by an Act Record in the EHR (Act Record is Persistent Evidence of Act Occurrence)
Acts have a chronology of occurrence	Act Records have a corresponding chronology
Acts are a common unit of service in health(care)	Act Records are a common unit of record of the EHR

EHR Interoperability Model

Section by Section, con't

3 - Act Record

- An Act Record documents each Act
- An Act Record is persistent evidence of Act occurrence
- An Act Record has an accountable Author
- The Act Record is the common EHR unit of record

4 - Act Record Attributes

- Act Record is comprised of attributes

EHR Interoperability Model

Section by Section, con't

5 - Health Record

- The Health Record is a chronology of Acts occurring in the course of health(care) delivery
- The Health Record is comprised of persistent Act Record(s)
- The Health Record may encompass single point in time, an encounter, an arbitrary period of time or a full lifetime

6 - Patient Encounter Record

- Encounter Record comprises Act Records related to a patient Encounter

7 - Patient Summary Record

- Creating a Summary Record is itself an Act
- An Act Record may be a summary of other Act Record(s)

EHR Interoperability Model

Section by Section, con't

8 - EHR Interoperability (Summary)

- Technical: Act Records are interchanged with secure and reliable transport
- Semantic: Act Records are interchanged with content and meaning preserved
- Process: Act records are interchanged in the course of the healthcare delivery process and promote continuity of that process

EHR Interoperability Model

Column by Column

A - Identifier

B - EHR Interoperability Assertion or Characteristic

- An *assertion* states a basic principle of EHR interoperability
- A *characteristic* specifies a discrete requirement of EHR interoperability and includes testable conformance criteria

C and on

- Derived from Column B Assertion or Characteristic

EHR Interoperability Model

Column by Column, con't

C - Elaboration

- Additional description of each EHR interoperability assertion or characteristic

D - Attribute Class

- Attribute class testable for each EHR interoperability characteristic

E - Example

F - Use Case Example

G - Legal Record Requirement?

- Realm specific, example profile

EHR Interoperability Model

Column by Column, con't

H-L - Conformance Criteria

- Per EHRS or application role
- Source - at point of record origination
- Outbound - at point of record transmittal
- Interchange standard
- Intermediary - during record interchange
- Inbound - at point of record receipt

EHR Interoperability Model

Column by Column, con't

M-O - Stakeholder Assurance

- Trust Span to Downstream Record User: Consumer/Patient, Provider, Record Author Perspective
- Trust Span from Upstream Record Source: Ultimate Record User Perspective

P - Standards Reference

Q - EHRS Functional Model Reference

EHR Interoperability Model

Column by Column, con't

R-S - For Future Consideration

T - CDAr2 Profile

- Common EHR Record Unit Requirements (Sections 3&4 only)

U - CDAr2 Testability Criteria

EHR Interoperability Model

Testability

EHRS/FM	EHR/IM
Conformance Testing - External to HL7	
• Certification – As a Conforming EHR-S product – By a Certification Authority (e.g., US CCHIT)	EHR Record Validation • TBD
• Expert Jury assessment and scoring	• Algorithmic test –EHR Record (instance or collection) • Expert Jury assessment and scoring

EHR Interoperability Model

Testable Artifacts

EHR Record at Rest

- Proprietary EHR Record
  - Vendor EHRS proprietary format
- Industry Standard EHR Record
  - EHR Common Record Unit (as proposed)

EHR Record in Transit, as an Interchange Artifact

- EHR Common Record Unit (as proposed)
- HL7 Clinical Document Architecture (CDA), Release 2
- HL7 v2/v3 Message
- CEN/ISO 13606 EHR Extract (using HL7 v3/CDA)
- Proprietary/Local EHR Transfer Format

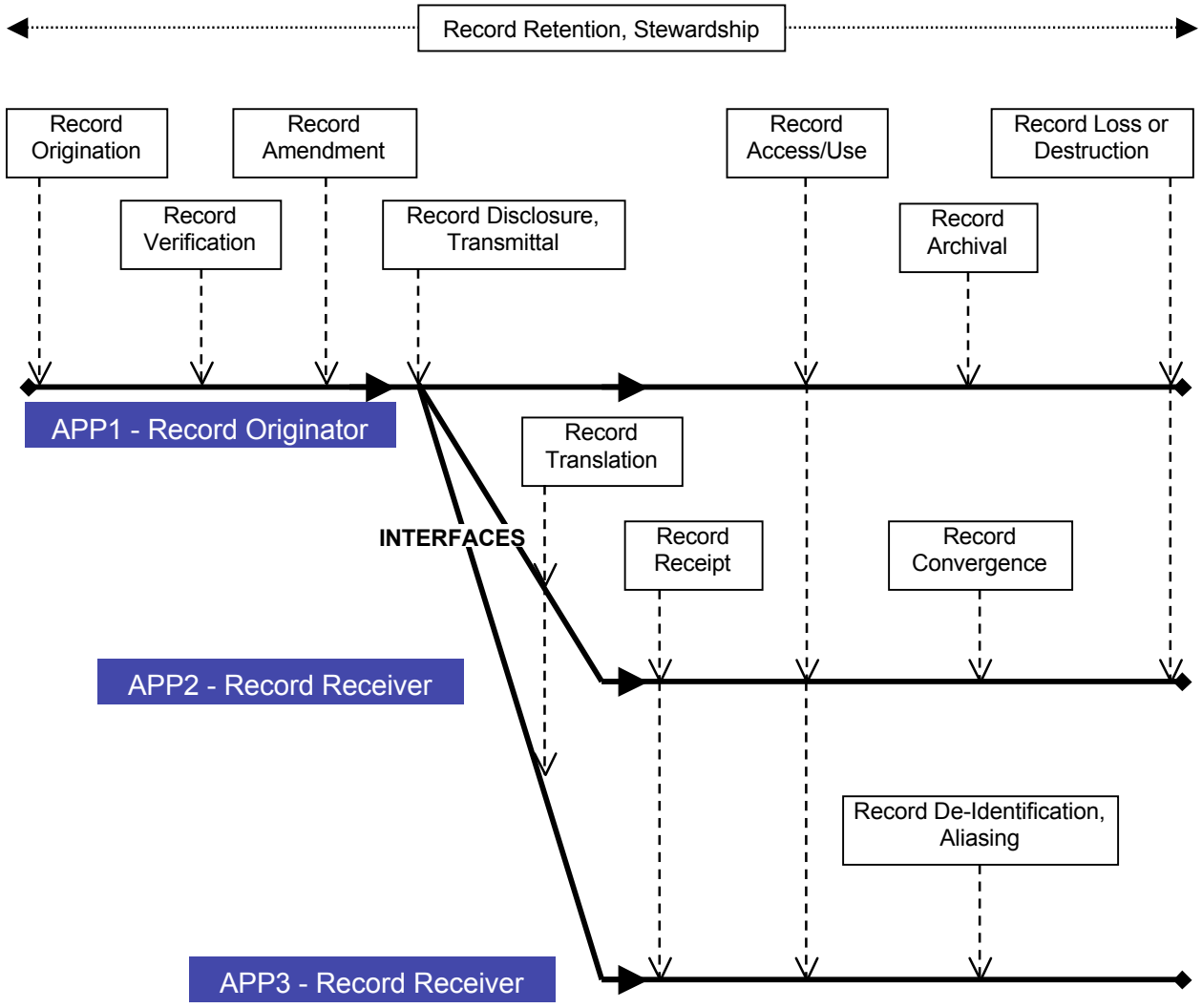
EHR Interoperability Model

Potential Point(s) of Testing

Lifecycle Events occurring at Point of Record:

- Origination and Retention
- Amendment
- Verification
- Access, View
- Translation
  - Language and Coding/Classification Scheme
- Transmittal and Disclosure
- Receipt and Retention
- De-identification, Aliasing, Re-Identification
- Archival

ISO 21089 - Key Trace Points in End-to-End Information Flow



EHR Interoperability Model

Next Steps

- Review and revise draft
  - Parking lot issues
- Prepare for public comment period
- Capture input and revise model
- Prepare draft for normative ballot

- Volunteers Welcome!!

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3 Complementary Models

- EHR System Functional Model
- EHR Interoperability Model
- EHR Lifecycle Model

- Each specifies:
  - Requirements
  - Testable conformance criteria

Complementary EHR/EHRS Models

Overview

	EHR System Functional Model (EHRS/FM)	EHR Interoperability Model (EHR/IM)	EHR Lifecycle Model (EHR/LM)
Focus	Functions of EHR Systems	Characteristics of Interoperable EHR Records	Key Audit/Trace Events in EHR Record Lifecycle
Specifies	~150 Functions	~100 Characteristics	16 Events
Status Aug 2007	• HL7 Normative • ANSI Approved • ISO Work Item	• HL7 DSTU • 2008: Normative?	• HL7 Draft in Development • 2007: DSTU?

EHR Lifecycle Model

- Lead
  - Gary L. Dickinson
- Working Draft in Development
  - Started January 2007

EHR Lifecycle Model

What is It?

- A working draft in development
- A common industry reference point
- A specification of lifecycle events for interoperable EHR records
- A framework for EHR record audit and traceability
- A supplement to the EHR Interoperability Model
  - Audit/trace points (per EHR/IM Section 3.19)

EHR Lifecycle Model

What is It? con't

- A structure to ensure record persistence and indelibility
- A framework for conformance testing
- An approach which is technology and vendor neutral

EHR Lifecycle Model

Section by Section

1 - Background

2 - Purpose

3 - Objectives

4 - Health(care) Delivery

5 - The Health(care) Act

6 - The Act Record

7 - The Act/Act Record Paradigm

8 - The Act Record Interchange Paradigm

EHR Lifecycle Model

Section by Section

9 - Events in the Act Record Lifecycle

10 - EHR Lifecycle Event Initiators

11 - Description of EHR Lifecycle Events

12 - System Roles in the EHR Record Lifecycle

13 - The Downstream EHR Record Lifecycle

14 - Audit and Traceability

15 - Conformance Criteria

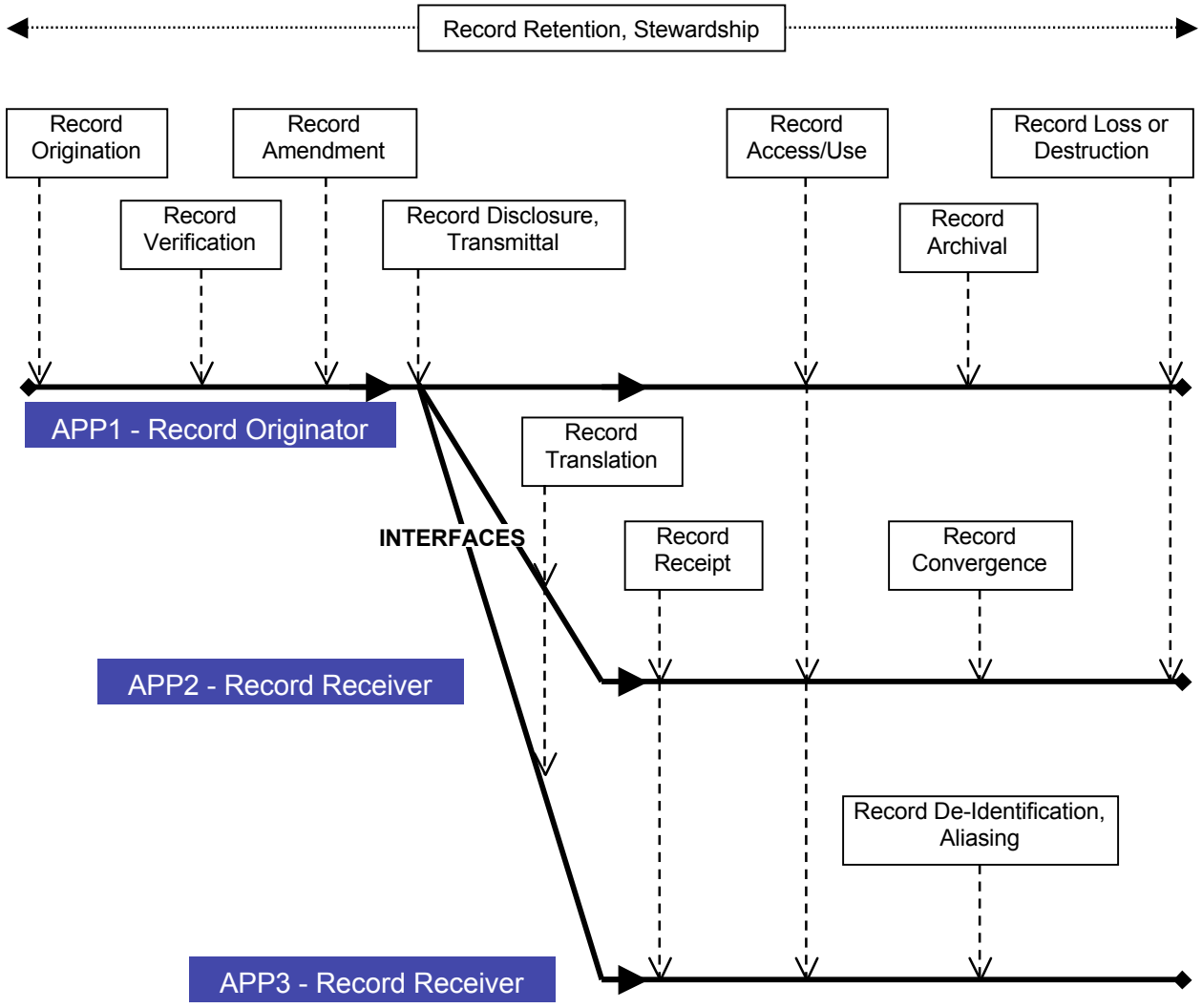
EHR Lifecycle Model

EHR Lifecycle Events

At Point of Record:

- Origination and Retention
- Amendment
- Verification
- Access, View
- Translation
  - Language and Coding/Classification Scheme
- Transmittal and Disclosure
- Receipt and Retention
- De-identification, Aliasing, Re-Identification
- Archival

ISO 21089 - Key Trace Points in End-to-End Information Flow



EHR Lifecycle Model

Next Steps

- Continue internal review and revision
- Prepare draft for public review and comment
- Capture input and revise model
- Prepare draft for DSTU ballot

- Volunteers Welcome!!

CDAr2 Reference Profile

- Lead
  - Calvin Beebe, Mayo Clinic
  - Co-Chair, HL7 Structured Documents TC
- Working Draft in Development

CDAr2 Reference Profile

What is It?

- A crosswalk of CDAr2 attributes vis-a-vis requirements of the EHR Interoperability Model
- A specification of CDAr2 as an implementation of the Common EHR Record Unit
  - Mapped to EHR/IM Sections 3&4
- A collaboration between HL7 TCs
  - EHR, Structured Documents, Security

CDAr2 Reference Profile

Now

- Sample profile embedded in DSTU
  - EHR/IM Columns T&U
- Requirements Covered by CDAr2
  - Currently 48 of 58
- 10 under Review, for Future
  - Non-Patient Specific Records
  - Access Control/Confidentiality Indicator
  - Record Audit/Traceability

CDAr2 Reference Profile

Next Steps

- Review profile in joint EHR/SD TC session
- Separate profile from EHR/IM
- Prepare for public review and comment
- Capture input and revise draft
- Prepare draft for profile ballot
- Align document and record architectures
  - CDAr2 Implementation Guide for EHR

- Volunteers Welcome!!

Legal Record Profile

- Lead
  - Michelle Dougherty, AHIMA
  - Facilitator, EHR TC Legal Aspects Team

Legal Record Profile

What is It?

- An assessment of EHR Interoperability Model requirements applicable to a fully formed, legally qualified record
  - Current and new requirements to be considered
- A validation/revision of current legal record profile
  - EHR/IM, Column G
- A US realm specific profile

Legal Record Profile

Next Steps

- Begin review
- Separate profile from EHR/IM
- Prepare draft for public review and comment
- Capture input and revise
- Prepare draft for profile ballot

- Volunteers Welcome!!

ONC/AHIC/HITSP Use Case Alignment

- Leads
  - Y1 EHR/Lab Results Reporting
    - Sherry Selover, Selover EDI Solutions
  - Y1 Consumer Empowerment
    - Kim Salamone, Health Services Advisory Group
  - Y1 Biosurveillance
    - Gora Datta, Cal2Cal

ONC/AHIC/HITSP Use Case Alignment

What is It?

- An assessment of how/where ONC/AHIC/HITSP use cases align with HL7 EHR/PHR Models
  - EHRS and PHRS Functional Models: functions invoked by use case
  - EHR Interoperability Model: record characteristics necessary to support use case
  - EHR Lifecycle Model: record lifecycle events invoked by use case

ONC/AHIC/HITSP Use Case Alignment

What is It? con't

- A framework based on 4 level use case hierarchy
  - Use case, scenario, event and action
- An analysis of:
  - Use case actions (Acts)
  - Persistent evidence of action occurrence (Act Records)
  - Act Record retention, interchange and lifecycle

ONC/AHIC/HITSP Use Case Alignment

Next Steps

- First use case analysis completed, draft available for review and comment
  - Year 1 - Care Delivery - EHR/Lab Reporting
- Teams forming for next two use cases
  - Year 1 - Population Health - Biosurveillance
  - Year 1 - Consumer Empowerment - Demographics, Medication History
- Prepare drafts for review and comment
- Capture input and revise documents
- Prepare for ballot (?)
- Volunteers Welcome!!

ISO 21089 - “Trusted End-to-End Information Flows”

- Lead
  - Gary Dickinson

ISO 21089 - “Trusted E2E Information Flows”

What is It?

- An ISO Technical Report, published 2004
- A candidate for promotion to a full normative standard
  - As a full ISO International Standard or Technical Specification
- A framework for end-to-end trusted information flows
  - Originally focused on messaging paradigms
  - Including audit/trace points

ISO 21089 - “Trusted E2E Information Flows”

Status

- Montreal, April 2007 - ISO TC215 Meeting
  - Agreed that this update should include flow of both transient messages and persistent health records
  - Agreed that the HL7 EHR Models, particularly the EHR/IM and EHR/LM, already incorporate the persistent health record perspective
  - Agreed (at least for now) to suspend further work on ISO 21089 in deference to completion and promotion of the HL7 EHR/EHRS Models to ISO TC215

ISO 21089 - “Trusted E2E Information Flows”

Status

- Montreal, April 2007 - ISO TC215 Meeting
  - Noted that the HL7 EHRS Functional Model
    - Passed HL7 normative ballot
    - Gained ANSI approval and
    - Prepared as an ISO new work item proposal (out for ballot)

Health Record Banking Alliance (HRBA)

- Lead
  - Gary Dickinson, HL7 EHR TC
  - William (Bill) Yasnoff, MD
    - Chair, HRBA

- HRBA website: http://www.healthbanking.org

Health Record Banking Alliance

What is It?

- An alliance promoting health record banks for retention of personal health records
- A framework combining many key concepts of robust health record management with aspects of financial banking
  - Trusted fiduciaries, personal health record accounts, privacy/security, consumer control...
  - Authorized “deposit” and “withdrawal” of health records to/from personal HRB account

Health Record Banking Alliance

What is It? con't

- A context where the Common EHR Record Unit (Act Record) could be utilized as HRB common currency

Health Record Banking Alliance

Next Steps

- Continue dialog with Dr. Yasnoff and HRBA
- Promote HRBA engagement with EHR TC
  - HL7 PHRS/FM Model
  - Common EHR Record Unit (for HRB)

- Volunteers Welcome!!

To Participate

Contact Gary Dickinson, Facilitator

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